



## UNITED STATE DEPARTMENT OF COMMERCE Patent and Trademark Office

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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO.

09/291,894

04/13/99 COLLINS

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17634-000520

020350 HM22/0607 TOWNSEND AND TOWNSEND AND CREW LLP TWO EMBARCADERO CENTER EIGHTH FLOOR

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EXAMINER

BRUMBACK,B

ART UNIT PAPER NUMBER

1642

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DATE MAILED:

06/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

## Office Action Summary

Application No.

09/291,894

Examiner **Brenda Brumback**  Group Art Unit 1642

Collins et al.



Responsive to communication(s) filed on	· · · · · · · · · · · · · · · · · · ·
☐ This action is <b>FINAL</b> .	
☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.	
is longer, from the mailing date of this communicati	ction is set to expire1 month(s), or thirty days, whichever ion. Failure to respond within the period for response will cause the 33). Extensions of time may be obtained under the provisions of
Disposition of Claims	
	is/are pending in the application.
Of the above, claim(s)	is/are withdrawn from consideration.
Claim(s)	is/are allowed.
Claim(s)	is/are rejected.
Claim(s)	is/are objected to.
	are subject to restriction or election requirement.
Application Papers  See the attached Notice of Draftsperson's Pa	tent Drawing Review, PTO-948.
☐ The drawing(s) filed on	•
☐ The proposed drawing correction, filed on	
☐ The specification is objected to by the Examir	
☐ The oath or declaration is objected to by the	Examiner.
Priority under 35 U.S.C. § 119	
Acknowledgement is made of a claim for fore	eign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFI	ED copies of the priority documents have been
received.	
received in Application No. (Series Cod	
•	on from the International Bureau (PCT Rule 17.2(a)).
*Certified copies not received:  Acknowledgement is made of a claim for don	nestic priority under 35 U.S.C. § 119(e).
•	
Attachment(s)  Notice of References Cited, PTO-892	
☐ Information Disclosure Statement(s), PTO-144	49, Paper No(s)
☐ Interview Summary, PTO-413	
☐ Notice of Draftsperson's Patent Drawing Revi	
☐ Notice of Informal Patent Application, PTO-15	52
SEE OFFICE A	ACTION ON THE FOLLOWING PAGES

## **DETAILED ACTION**

## Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-3, 6-10, 21, 35, and 46-51 drawn to chimeric human RSV comprising RSV A combined with human RSV B, classified in class 424, subclass 199.1 or 211.1.
  - II. Claims 1, 4, 5, and 11, drawn to chimeric RSV wherein the heterologous gene is selected from NS1, NS2, N, P, M, SH, M1(ORF1), M2(ORF2), L, F, and G, classified in 424, subclass 199.1 or 211.1.
  - III. Claims 1, 12, 13, 18-20, and 22, drawn to chimeric RSV further modified by attenuating mutations present within a panel of biologically derived mutant RSV strains, classified in class, 424 subclass 199.1 or 211.1.
  - IV. Claims 1, 12, 14, 20, and 22, drawn to chimeric RSV incorporating temperature sensitive mutations, classified in class 424, subclass 199.1 or 211.1.
  - V. Claims 1, 12, 15, 20, and 22, drawn to chimeric RSV incorporating mutations from cold-passaged attenuated RSV, classified in class 424, subclass 199.1 or 211.1.

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- VI. Claims 1, 16, 17, 20, and 22, drawn to chimeric RSV comprising substituted F and G genes and further modified to incorporate attenuating point mutations, classified in class 424, subclass 199.1 or 211.1.
- VII. Claims 1 and 22-24, drawn to chimeric RSV further comprising a nucleotide modification specifying a phenotypic change, wherein a SH, NS1, NS2, M2ORF2, or G gene is deleted, classified in class 424, subclass 199.1 or 211.1.
- VIII. Claims 1, 22, and 25-29, drawn to chimeric RSV further comprising a deletion, insertion, substitution or rearrangement of a cis-acting regulatory sequence, classified in class 424, subclass 199.1 or 211.1.
- IX. Claims 1, 22, and 30-33, drawn to chimeric RSV incorporating a non-RSV gene, classified in class 424, subclass 199.1 or 211.1.
- X. Claims 1 and 34, drawn to chimeric RSV comprising human RSV combined with bovine or murine RSV, classified in class 424, subclass 199.1 or 211.1.
- XI. Claims 1 and 36, drawn to chimeric RSV which is a subviral particle, classified in class 424, subclass 199.1 or 211.1.
- XII. Claims 1 and 37-45, drawn to methods of stimulating the immune system, classified in class 424, subclass 199.1 or 211.1.
- XIII. Claims 52- 55 drawn to an isolated polynucleotide molecule comprising a chimeric RSV genome combined with a heterologous gene, wherein the heterologous gene

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encodes a RSV F, G, or SH glycoprotein, classified in class 424, subclass 199.1 or 211.1.

- XIV. Claims 52, and 56-60, drawn to an isolated polynucleotide molecule comprising a chimeric RSV genome of subgroup A combined with a heterologous gene from subgroup B, classified in class 424, subclass 199.1 or 211.1.
- XV. Claims 52 and 61-63, drawn to an isolated polynucleotide molecule comprising a chimeric RSV genome and further comprising a nucleotide modification specifying a phenotypic change, classified in class 424, subclass 199.1 or 211.1.
- XVI. Claims 64 and 65, drawn to methods for producing an infectious attenuated chimeric RSV, classified in class 424, subclass 199.1 or 211.1.
- 2. The inventions are distinct, each from the other because of the following reasons:

  The products of groups I-XI, and XIII-XV have different structures and different immunological properties.

Inventions I and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the chimeric RSV of Group I can be used in the materially different processes of diagnostic testing and affinity purification of antibodies.

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The methods of Groups XII and XVI have different method steps and are for different

purposes.

It is noted that certain of the claims appear in multiple groups. Claims which appear in

more than one group will be examined with the elected group to the extent that they read on that

group.

3. Because these inventions are distinct for the reasons given above and have acquired a

separate status in the art because of their recognized divergent subject matter, restriction for

examination purposes as indicated is proper.

4. Due to the complexity of the claims, the restriction requirement is in writing. Applicant is

advised that the reply to this requirement to be complete must include an election of the invention

to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the

inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the

fee required under 37 CFR 1.17(i).

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB June 5, 2000

Brenda Brumback,
Patent Examiner